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AUG 20 2007

Application Serial No. 10/566,333  
Attorney Docket No. S2082/20004  
Amendment Dated, August 20, 2007

### REMARKS/ARGUMENTS

By this Amendment, Claims 1, 9, 21, 31, 38, 44 and 45 have been amended. Thus, Claims 1-70 are pending.

The Examiner has rejected Claims 21 and 31 based on 35 U.S.C. §112, second paragraph as being indefinite; in particular, there was insufficient antecedent basis for the term "driver protrusions". To that end, Applicants have amended Claims 21 and 31 to delete the word "driver" and Applicants respectfully request that the §112 rejection be withdrawn.

The Examiner has rejected Claims 1, 9, 38, 44 and 45 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Publication No. 2002/0193746 (Chevallier) and/or U.S. Patent No. 6,319,233 (Jansen).

Applicants respectfully disagree for the following reasons. Chevallier discloses an automatic syringe that uses concentrically moveable inner and outer sheaths that cooperate to provide a safety cover for the needle once the drug has been delivered. However, Chevallier fails to provide any structure that conceals the needle prior to injection. This is shown in Figs. 1-2, before injection, the needle 14 is exposed:

[0046] FIGS. 1 to 4 show the device ready in the waiting, retracted position with the inner sheath 18 inside the sheath 16. In this position, the retaining tongues are hooked and the spring 34 is loaded, while the needle 14 of a syringe placed inside the device projects beyond the front ends of the sheaths. (emphasis added, Chevallier).

As a result, the user of the Chevallier device is not protected from any accidental needle prick prior to use. To that end, Applicants have amended Claims 1, 9, 38, 44 and 45 to more clearly distinguish over Chevallier by specifying that the needle is positioned within the shield prior to injector device activation said shield prior to said trigger being

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actuated.

With regard to Jansen, the Jansen injector requires user intervention to deploy its shield:

*Following removal of the needle 18 from the patient, the user applies a greater force to the plunger rod than that applied during injection. Such force causes axial displacement of the end fitting, the spring and the shield with respect to the holder. The distance between the annular wall 66 of the end fitting (or the flange 24) and the second abutment surface 44 is sufficient to allow the shield stop member 58 to move far enough axially to where its retention by the holder stop member 48 is overcome by the force of the spring. In the preferred embodiment, this is accomplished as the inclined surfaces of the stop members slide past each other. The holder stop member 48 is also displaced radially as such sliding occurs due to the flexibility of the holder body portion which adjoins it. (emphasis added, Jansen, col. 6, lines 39-53).*

As well as Jansen's second embodiment (Figs. 14-19):

In operation, the device 100 is employed in substantially the same manner as a conventional syringe, starting with the arrangement of elements shown in FIG. 16. The user pushes the plunger rod using his thumb while the flanges of the holder are engaged by the index and middle fingers of the same hand. Once the piston has been moved to an abutting position with the end of the syringe barrel, further pressure exerted by the user on the plunger rod causes axial movement of the syringe itself. Due to the abutting relation of the coils of the spring to each other, the spring in effect forms a solid connection between the syringe flange and the proximal end of the shield. Axial movement of the syringe accordingly causes corresponding axial movement of the shield until the collar 114 moves beyond the stop member 116, as shown in FIG. 18. Expansion of the spring causes the shield to move to an extended position, as shown in FIG. 17. (emphasis added, Jansen, col. 7, line 66 to col. 8, line 14).

In contrast, the protrusions 312 of the driver fingers 311 slide off the barrel 511 allowing the fingers 311 to deflect toward the reduced-diameter neck N of the cartridge 500<sup>1</sup>, which automatically urges, or triggers or deploys the shield placement, or automatically conceals the needle within the shield. To that end, Applicants have amended Claims 1, 9, 38, 44 and 45 to specify the automatic deployment of the shield, thereby distinguishing from the user-intervening action required to deploy the shield in the Jansen device.

<sup>1</sup> See p. 21 of the present application (WO 2005/009515), lines 10-17.

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Thus, in view of the amendments to Claims 1, 9, 38, 44 and 45 and their supporting arguments, Applicants respectfully submit that these claims are patentable over the art of record and respectfully request that the §102(b) rejection be withdrawn.

The Examiner has rejected Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70, 19-21, 50-52 and 58-59 under 35 U.S.C. §103(a) as being unpatentable over Chevallier and/or Jansen in view of U.S. Patent Publication No. 2003/01005430 (Lavi, et al.) and/or U.S. Patent No. 5,599,309 (Marshall)<sup>2</sup>.

Applicants respectfully disagree for the following reasons.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the Examiner's assertion that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated" changes the principle of operation of the primary reference Chevallier which is to drive the stopper, and dispense the medication, upon activation of the syringe (Chevallier, p.1, paragraph 0009). Such a proposed modification is not permitted under MPEP §§2143/VI and 2145/III. Thus, for all of these reasons, Applicants respectfully submit that Claim 2 is patentable over the art of record.

Claim 3 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the Examiner's assertion citation of Figs. 6-9 of Marshall still does not render the invention of Claim 3 as being obvious for the following reasons. Fig. 6 forms a second embodiment of

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<sup>2</sup> In rejecting Claims 16-18, 53-57, 60, 22-25, 39-42, 26, 28-31, 49, 65-66, 69, 27, 62, 32-34, 43, and 67-68 under §103(a), the Examiner asserts that because components are found in the cited art, this renders these particular claims as being obvious. One of the criteria of establishing a prima facie case of obviousness is that the prior art references must teach or suggest all of the claim limitations (MPEP §2143), not just components mentioned in the claims.

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Marshall which appears to use the same nose 3 of the first embodiment (Figs.1-2). In that first embodiment, there appears to be no relative movement of the nose 3<sup>3</sup> with respect to the barrel 1. The third embodiment of Marshall shown in Figs. 7-12 uses a nose 42 which screws into the forward end of cylindrical portion 41 of a sloping shoulder 40 of barrel 31 that is also screwed onto the forward end of the body 31<sup>4</sup>. See Marshall, col. 4, lines 14-19. Thus, there is no "movement of any shield with the respect to the housing" as specified in Claim 3. As a result, even if one skilled in the art were to combine Chevallier with Marshall, this would still not render the invention obvious. To that end, Applicants respectfully submit that for all of these reasons, Claim 3 is patentable over the art of record and respectfully request that the §103(a) rejection be withdrawn.

Claim 4 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 5 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 7 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 10 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 11 is dependent upon Claim 10 and is patentable for the same reasons.

Claim 12 is dependent upon Claim 10 and is patentable for the same reasons.

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<sup>3</sup> Marshall, col. 2, lines 52-54 specifies that "a nose piece 3 is fitted into the mouth of the barrel 1 and provides a shield and a guide for a capsule 4 with a needle 5." The term "fitted" appears to support a "fixed" relationship between the nose 3 and barrel 1.

<sup>4</sup> It should be also noted that with respect to this third embodiment of Marshall, Fig. 9 depicts the "after use" state of the injector which clearly shows an exposed needle 36, in contravention to the limitations of Claim 1 of the present invention.

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Claim 13 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 15 is dependent upon Claim 14 and is patentable for the same reasons.

Claim 16 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 17 is dependent upon Claim 9 and is patentable for the same reasons.

Furthermore, the Examiner fails to identify where the limitation of this claim, namely, a driver including a set of barrel supports extends longitudinally and which slide on the external surface of the barrel during injection is suggested in the combination of Chevallier (or Jansen) with Lavi (or Marshall).

Claim 18 is dependent upon Claim 17 and is patentable for the same reasons. Furthermore, the Examiner fails to identify where the limitation of this claim, namely, cartridge barrel supports are adapted to detect the end of the barrel and release the driving unit, is suggested in the combination of Chevallier (or Jansen) with Lavi (or Marshall).

Claim 19 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 20 is dependent upon Claim 19 and is patentable for the same reasons.

Claim 21 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 22 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 23 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 24 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 25 is dependent upon Claim 23 and is patentable for the same reasons.

Claim 26 is dependent upon Claim 9 and is patentable for the same reasons.

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Claim 27 is dependent upon Claim 9 and is patentable for the same reasons.  
Claim 28 is dependent upon Claim 9 and is patentable for the same reasons.  
Claim 29 is dependent upon Claim 28 and is patentable for the same reasons.  
Claim 30 is dependent upon Claim 28 and is patentable for the same reasons.  
Claim 31 is dependent upon Claim 21 and is patentable for the same reasons.  
Claim 32 is dependent upon Claim 28 and is patentable for the same reasons.  
Claim 33 is dependent upon Claim 32 and is patentable for the same reasons.  
Claim 34 is dependent upon Claim 32 and is patentable for the same reasons.  
Claim 35 is dependent upon Claim 28 and is patentable for the same reasons.  
Claim 36 is dependent upon Claim 28 and is patentable for the same reasons.  
Claim 37 is dependent upon Claim 33 and is patentable for the same reasons.  
Claim 39 is dependent upon Claim 28 and is patentable for the same reasons.  
Claim 40 is dependent upon Claim 39 and is patentable for the same reasons.  
Claim 41 is dependent upon Claim 39 and is patentable for the same reasons.  
Claim 42 is dependent upon Claim 39 and is patentable for the same reasons.  
Claim 43 is dependent upon Claim 38 and is patentable for the same reasons.  
Claim 46 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 47 is dependent upon Claim 46 and is patentable for the same reasons.  
Claim 48 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 49 is dependent upon Claim 48 and is patentable for the same reasons.  
Claim 50 is dependent upon Claim 45 and is patentable for the same reasons.

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Claim 51 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 52 is dependent upon Claim 51 and is patentable for the same reasons.  
Claim 53 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 54 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 55 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 56 is dependent upon Claim 55 and is patentable for the same reasons.  
Claim 57 is dependent upon Claim 55 and is patentable for the same reasons.  
Claim 58 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 59 is dependent upon Claim 58 and is patentable for the same reasons.  
Claim 60 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 61 is dependent upon Claim 60 and is patentable for the same reasons.  
Claim 62 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 63 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 64 is dependent upon Claim 63 and is patentable for the same reasons.  
Claim 65 is dependent upon Claim 63 and is patentable for the same reasons.  
Claim 66 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 67 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 68 is dependent upon Claim 67 and is patentable for the same reasons.  
Claim 69 is dependent upon Claim 45 and is patentable for the same reasons.  
Claim 70 is dependent upon Claim 45 and is patentable for the same reasons.

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Thus, Applicants respectfully submit that, as amended, Claims 1-70 are now in condition for allowance. Accordingly, prompt and favorable examination on the merits is respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for initial examination and allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

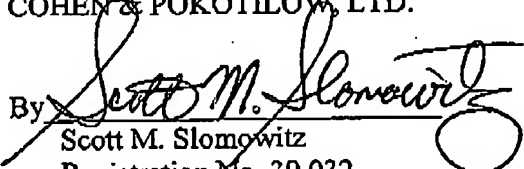
Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

August 20, 2007

Please charge or credit our  
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to effect entry and/or ensure  
consideration of this submission.

By

  
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